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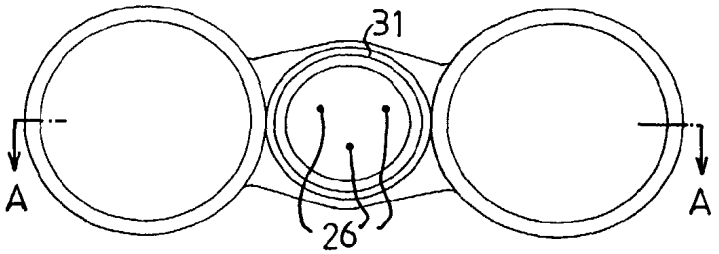
(54) Title: METHOD AND DEVICE FOR MEASUREMENT OF HUMIDITY TRANSPORT TO AND FROM A VENTILATOR



(57) Abstract: The method is characterized in particular in that the measurement comprises the measurement of the ratio between the collected weight of water vapour in an inspiration or expiration, respectively, of respiration gas and the inspired or expired, respectively, volume of the respiration gas, and in that the respiration gas, in proportion to the inspiration of expiration gas flow, respectively, is supplied to a hygroscopic hygrometer (25) for moisture exchange between the supplied respiration gas and the hygroscopic substance of the hygrometer, the output signal from the hygrometer constituting a measure of said ratio. The invention also relates to a device for measuring moisture transport.

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Method and device for measurement of humidity transport to and from a ventilator

The present invention relates to a method and a device for measuring moisture transport to and/or from a ventilator patient.

When caring for artificially ventilated patients, it is essential to monitor the amount of moisture which the patient inhales and exhales. If the inhaled amount of moisture during a long sequence of inhalations is small relative to that exhaled, the patient's air passages can be damaged by drying out and, if it is great, water can collect in the lungs. (Maire P. Shelly, Intensive Care Rounds, Humidification, Zeneca, June 93).

Each inhalation and exhalation involves a transport of moisture to or from the patient. The transport flow is dependent on the mean volumetric moisture content which is defined as the weight of water vapour in one breath divided by the volume of the breath (unit: mg/liter).

Both the instantaneous moisture content of respiration gas as well as the instantaneous flow at the connection point of the ventilator to the patient vary with time during a respiratory cycle and can also be variable in different ways (there is generally no co-variation). For this reason, a measure of the mean volumetric moisture content cannot be reliably obtained by merely measuring, for example, average relative humidity over time.

The invention relates as well to a device for measuring moisture transport in respiration gas.

The present state of the art

Measurement of the mean volumetric moisture content to and from the patient for continuous monitoring is not available today and no equipment is known which is classed as a medical technological product, as is required for routine use.

Using the definition of the mean volumetric moisture content and measuring the moisture content in a mixing chamber, where the entire tidal volume of inhaled or exhaled gas is collected and stirred, is not possible. The large volume of such a chamber would adversely affect the ventilation of the patient's lungs. Stirring is for evening out differences in properties of gas from various portions of a respiration cycle.

It is possible to reduce the volume of the chamber by leading to it a representative portion of inhaled or exhaled gas with the aid of a shunt, as in Fig. 1 (see also WO91/04067).

Fig. 1 shows a ventilator 1 with conduits 2, 3 for inhaling and exhaling, which are coupled together in a Y-piece 4. The direction of flow is indicated by arrows.

The chamber gas is kept well mixed in such a manner that the average staying time in the chambers 5, 6 is substantially longer than the duration of one respiration cycle. The mean volumetric moisture content to and from the patient 7 is thus equal to the water vapour content of the chamber gas (unit: mg/liter). The content is measured, for example, with a combination of relative humidity (RH) sensors and temperature sensors or with a dew point sensor. Despite the reduction in size through the shunt, this device is too bulky for routine use, especially since the chambers and their connections 8, 9 to the hose or pipe through which the respiration gas flows one way, the patient conduits 2, 3 are heated to avoid condensation of water. The extraction of gas from the patient conduit must be done close to the patient, and there, there is not much space. If the extraction is done far away from the patient, the measurements will be less reliable since moisture can condense in the patient conduits.

One variant of mixing chamber is placed at the ventilator outlet 10. The chamber consists of a tube 11, containing an RH-sensor as disclosed in the Swedish Patent

8900979-9, placed in a T 12. Both pipe and T are standardized coupling components for respiration circuits. This device as well is too bulky for placement close to the patient in routine use.

An RH-sensor and possibly a temperature sensor are sometimes placed in the patient conduit, i.e. without using a mixing chamber. In order to avoid the formation of condensation, the sensors or adjacent parts of the patient conduit are heated. Since there is no mixing chamber, in practice there is assumed either constant flow or constant moisture content of the gas flowing in the patient conduit during a respiration cycle. The gas flow varies greatly, however, during the respiration cycle, typically between zero and 1 liter/sec. In practice therefore, constant moisture content is assumed, but it is not always the case. A patient humidifier can, for example, provide a relatively low moisture content when the flow of gas therethrough is greatest.

RH-sensors or hygrometers, together with temperature sensors have also been connected to the conduit 13 having gas flow in two directions. Constant moisture content is in practice presupposed and only extremely fast RH-sensors can be used.

A weakness of all the known technology, considering routine use requirements, is, in addition to the bulky dimensions of the device, the complicated calibration of a moisture sensor.

The purpose of the invention

With a method and a device according to the invention, it should be possible to routinely and continually measure moisture transport to and from an artificially ventilated patient at reasonable cost. The device must be classifiable as a medical product, fulfilling i.a. all the requirements of reliability and patient safety. Satisfactory hygiene is provided by only one patient using components which are in contact with respiration gas. The moisture content of the respiration gas is allowed to vary during

the respiration cycle. The measure result is used e.g. for monitoring and/or controlling the patient humidifier.

This purpose is achieved by a method as defined in the accompanying claim 1 and by a device as defined in the accompanying claim 8. Preferred embodiments are defined in the dependent claims.

Description of the drawings

Fig. 1 shows prior art for measuring moisture transport

Fig. 2 shows the principle of the invention in a shunt

Fig. 3 shows the principle of the invention with a side chamber

Fig. 4 shows a preferred embodiment of a device according to the invention

Fig. 5 shows a preferred embodiment of a portion of a device according to the invention.

The principles of the invention

According to the prior art, respiration gas, or a representative portion thereof, is collected and mixed in a chamber so that an essentially homogeneous gas is obtained. According to the principle of the invention, the respiration gas is collected and mixed substantially not in the gas phase but in a solid or liquid substance. This makes a mixing chamber possible with substantially reduced dimensions (the moisture condenses in the substance). The substance in question must be hygroscopic, i.e. easily absorbing and giving off moisture Here follows the description of how a hygroscopic moisture sensor can be used for this purpose.

The function of the mixing chamber, containing a hygroscopic moisture sensor or hygrometer, is analyzed below. The sensor is, for example, of the type described in Swedish Patent 8900979-9, where the hygroscopic substance is an electrolyte in a liquid phase, e.g. an aqueous solution of lithium chloride or calcium chloride, both

strongly hygroscopic. The unique capacity of these solutions to exchange moisture with flowing respiration gas is well known from their use in moisture exchangers.

A hygroscopic sensor in moisture equilibrium with the surrounding gas has a constant moisture content, the size of which is determined by the moisture content of the surrounding gas.

Fig. 2 shows a chamber 14 in a shunt from a patient conduit 15. The chamber has an inlet 16, an outlet 17 and a hygroscopic sensor 18. It is presupposed that the temperature is known and is sufficiently high so that no condensation of water will occur.

The mean volumetric moisture content to and from an artificially ventilated patient does not change sharply. There is essentially a steady state during, say, ten breaths.

The hygrometer exchanges moisture with the respiration gas in the chamber, i.e. moisture flows due to the strongly hygroscopic effect to and from the sensor. This moisture exchange (unit: mg/sec) takes place during each breath and is essentially determined by two factors:

a) The gas flow through the chamber 14, which is proportional to the gas flow in the patient conduit (unit: liter/sec). The larger the gas flow is, the greater will be the supply of water molecules which can be absorbed by the hygroscopic substance, and vice versa.
b) The difference (unit: mg/liter) between the moisture content of the gas in the chamber and the moisture content of the gas in a thin layer closest to the surface of the sensor. The greater the difference in content is, the greater will be the hygroscopic effect.

The moisture transfer, i.e. the moisture transport between the gas in the patient conduit and the gas in a thin layer closest to the surface of the hygroscopic substance of the sensor, can thus be expressed as (unit: mg/sec):

$$\text{Constant} = F(t)\,[c_p(t) - c_g(t)]$$

	t	time variable [s]
5	F(t)	gas flow in patient conduit [liter/sec]
	$c_p(t)$	moisture content of the gas in a patient conduit [mg/liter]
	$c_g(t)$	moisture content in a gas layer closest to the surface of the sensor [mg/liter]

10 It is suitable to make the device so that the moisture content of the sensor varies relatively little during a respiration cycle as a result of moisture exchange with the respiration gas. This can be effected by selecting suitable dimensions, i.e. the cross-section of the inlet 16 and the amount of hygroscopic substance in the sensor. The moisture content of the sensor is thus practically constant during a respiration cycle, 15 and as a result thereof, the hygroscopic substance maintains a constant moisture content in a thin gas layer closest to the surface of the sensor.

The moisture exchange is zero when computed over one respiration cycle, since the state is essentially steady.

20 $$\int_0^T F(t)[c_p(t) - c_g(t)]dt = 0$$

T is the duration of the breath cycle. Since c_g is constant during the respiration cycle we have

25 $$c_g = \frac{\int_0^T F(t)\, c_p(t)\, dt}{\int_0^T F(t)\, dt}$$

30

In the numerator, there is the weight of the moisture in the breath and in the denominator, there is the volume of the breath. c_g is thus the correct measurement unit, i.e. the mean volumetric moisture content.

A non-hygroscopic sensor, which is described in WO91/04067, in the chamber 14 one would have measured the mean time value of $c_p(t)$, which is only correct in a special case.

The sensor is calibrated in a known manner in stationary air of known humidity and temperature, which provides the relationship between the output unit of the sensor (depends on electrical conductance or capacitance) and the moisture content c_g within the temperature range in question.

Nothing prevents making the chamber volume small since moisture is absorbed and given off continuously to and from the hygroscopic substance of the sensor. This is in contrast to the known mixing chamber, in which collection and mixing occur substantially in a gas phase. That the dimensions of the chamber can be reduced so radically is an important insight in achieving the purpose of the invention.

The analysis also applies to non-shunted mixing chambers, as long as the moisture exchange between the gas in the patient conduit and the sensor is determined by the two factors a) and b). Fig. 3 shows an example of such a connection. The factor a) is formulated in this case in such a way that the gas exchange between a chamber 19, containing a sensor 20, and a patient conduit 21 is proportional to the gas flow through the patient conduit. The gas exchange should largely occur by convection (eddies) and to a minor extent by diffusion. Optimisation is done by selecting dimensions for the opening 22 and the amount of hygroscopic substance in the sensor 20.

Sensors according to Swedish Patent 8900979-9 are particularly suitable as sensors in view of the fact that the conductance of the sensor is a measure of the moisture content of the sensor, even when the moisture is incompletely spread out within the sensor.

Description of preferred embodiments of the invention

A measuring device according to the preceding principles can be realized in a number of ways. The following examples are built on the use of a sensor in accordance with Swedish Patent 8900979-9 as a sensor.

The sensor is placed inside a capsule, the wall of which has portions which allow the passage through it of gas in proportion to the surrounding gas flow. The wall can be fibrous, porous or perforated, and the capsule can be placed inside the patient conduit. In order to avoid condensation water, the patient conduit is heated locally.

For the sake of simplicity, a preferred embodiment is based on the chamber 19 in Fig. 3 and will be described in more detail below.

Fig. 4 shows a sensor configuration with a Y-piece 23 with side chamber 24, containing sensor 25. To the contact pin 26 of the sensors (two wires from sensors are consolidated into one) there is connected an outer contact 30, having, as can be seen in the partial section of Fig. 5, a cylindrical heat conducting shield 27, which fits into a cylindrical slot 31. The shield 27 is heated by an annular heating element 32, self-regulating or controlled by a temperature sensor 28, so as to prevent condensation from forming in the chambers 24. A suitable chamber temperature is 42°C. 29 designates a sensor contact comprising e.g. a plastic or rubber plug with contact pins 26 therein. The flow direction of the respiration gas is indicated by arrows in Fig. 4.

Fig. 4 has left out that which can be needed to prevent respiratory medicine in aerosol form from reaching the sensor and affecting it. Measures can be based on the

fact that aerosol particles do not readily change a direction of movement, that they can be captured in a filter or by closing the chambers 24 when the medicine is administered.

The embodiment has a number of advantages.

The measurement of the mean volumetric ratio content takes place close to the branch point of the Y-piece, which eliminates unreliability of measurement arising when water condenses between the measuring point and the branch point. If the respiration conduits between the measuring point and the branch point are kept condensation-free by heating, the measuring point can, of course, be far from the patient, i.e. close to a patient humidifier. This latter case is analogous to the case described in relation to Figs. 4 and 5, and the chambers 24 are in an H-shaped connecting piece, located between a patient humidifier and a Y-piece.

A complete respiration circuit containing a Y-piece can be delivered in sterile condition to the user. Assembly of the sensor at the user would be time-consuming and could involve hygienic risks.

The Y-piece is insignificantly larger and weighs insignificantly more than a conventional Y-piece.

The Y-piece is manufactured efficiently by assembling the sensor with associated contact in an injection-moulded part.

The dimensions of the heating elements are small, the applied current is small and the electric wires for sensors, heating elements and temperature sensors can be placed in a single cable, running along the patient conduits.

Of physiological interest is the ratio between inhaled and exhaled moisture amounts, which warrants the use of two chambers, one connected to the inspiration conduit and one similar chamber connected to the expiration conduit. If the measured quantity is selected as the ratio between the output values of the two sensors, there is obtained a simple and accurate electrical/electronic signal processing design. The sensors do not need to be calibrated. It is sufficient that the user balance them electrically/electronically so that the ratio will be one before the Y-piece is connected to the patient. Sensors in accordance with Swedish Patent 8900979-9 can be manufactured in identical pairs, requiring neither calibration, nor balancing.

Typical data for sensors in accordance with Swedish Patent 8900979-9:

Length	15 mm
Diameter	3 mm
Moisture content	1 mg

The mean volumetric moisture content of expired gas at the Y-piece is typically 35 mg/litre.

A suitable value of the ratio between $c_{g,i}$ (inspiration) and $c_{g,e}$ (expiration) is 0.9.

Claims

1. Method of measuring moisture transport to and/or from an artificially ventilated patient, **characterized** in that the measurement comprises measurement of the ratio between the collected weight of water vapour in an inspiration or expiration, respectively, of respiration gas and the inspired or expired volume, respectively, of the respiration gas, and in that the respiration gas, in proportion to the inspiration or expiration gas flow, respectively, is supplied to a hygroscopic hygrometer (18, 20, 25) for moisture exchange between the supplied respiration gas and the hygroscopic substance of the hygrometer, the output signal from the hygrometer constituting a measure of said ratio.

2. Method according to claim 1, **characterized** in that the hygrometer with its hygroscopic substance is arranged in a chamber (14, 19, 24), which is in communication with a conduit (15, 21) for respiration gas.

3. Method according to claim 1 or 2, **characterized** in that the conductance of the hygrometer constitutes a measure of the current moisture content.

4. Method according to claim 1, 2 or 3, **characterized** in that at least one hygrometer (25) is arranged where a gas conduit for inspiration gas and a gas conduit for expiration gas come together into a common gas conduit running to the patient, measurement being effected substantially where the conduits come together, being thereby close to the patient.

5. Method according to claim 1, 2, 3, or 4, **characterized** in that two hygrometers (25), preferably of substantially the same type, one for taking measurements of the inspiration gas and one for taking measurements of the expiration gas, are arranged for measurement so that a ratio between the respective output signals is

provided for measuring of a ratio between moisture in the inspired and expired respiration gas.

6. Method according to claim 1, 2, 3, 4, or 5, **characterized** in that hygrometers (18, 20, 25) are used, the hygroscopic substance of which comprises an electrolyte in liquid phase, preferably an aqueous solution of lithium chloride or calcium chloride, the conductance of which is a measure of the total moisture content.

7. Method according to claim 2, 3, 4, 5, or 6, **characterized** in that said chambers are heated, preferably to ca 42°C, to avoid condensation of respiration gas.

8. Device for measuring moisture transport to and/or from an artificially ventilated patient, **characterized** in that there are devices (18, 20, 25) for measuring the ratio between the collected weight of water vapour in an inspiration or expiration, respectively, of respiration gas and the inspired or expired, respectively, volume of the respiration gas, and in that there are means (14, 19, 24) for conducting, to a hygroscopic hygrometer (18, 20, 25), respiration gas in proportion to the inspiration or expiration gas flow for moisture exchange between the supplied respiration gas and the hygroscopic substance of the hygrometer, the output signal from the hygrometer constituting a measure of said ratio.

9. Device according to claim 8, **characterized** in that the hygrometer with its hygroscopic substance is arranged in a chamber (14, 19, 24) in communication with a conduit (15, 21) for inspiration gas.

10. Device according to claim 8 or 9, **characterized** in that at least one hygrometer (25) is arranged substantially where a gas conduit for inspiration gas and a gas conduit for expiration gas come together into a common gas conduit running to

the patient, making measurement possible substantially where the conduits come together and thus preferably close to the patient.

11. Device according to claim 9 or 10, **characterized** in that two, preferably substantially identical, hygrometers (25) are aranged with individual chambers (24), where one chamber with hygrometer is arranged to be supplied with respiration gas from a conduit for inspiration gas and the other chamber is arranged to be supplied with expiration gas from a conduit for expiration gas.

12. Device according to claim 11, **characterized** in that a measurement configuration comprising the two chambers with their respective hygrometers is arranged in a, preferably essentially Y-shaped, coupling piece (23), intended to join a conduit for inspiration gas, a conduit for expiration gas and a gas conduit running to the patient.

13. Device according to claim 11 or 12, **characterized** in that there are devices for signal-processing of output signals from the respective hygrometer so that a ratio between the respective output signals is generated for measuring a ratio between moisture of the inspired and the expired respiration gas, respectively.

14. Device according to claim 12 or 13, **characterized** in that the measurement configuration comprises a terminal block (29), which supports the chambers (24) and to which the signal conduits of the hygrometers lead for external connection.

15. Device according to one of claims 9-14, **characterized** in that means (27, 28, 32) are arranged for heating said chambers (14, 19, 24), preferably to ca 42°C, to avoid condensation of respiration gas.

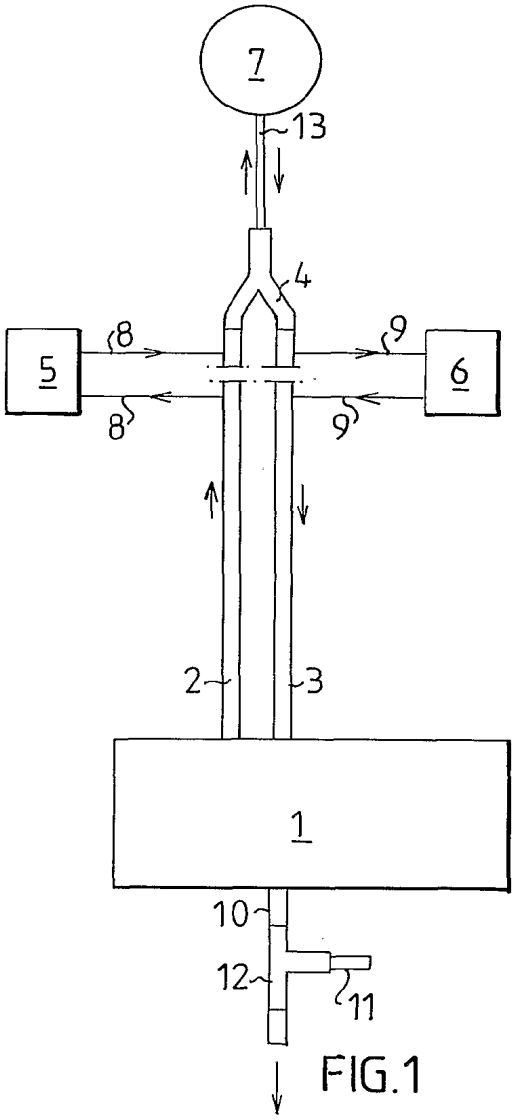


FIG.1

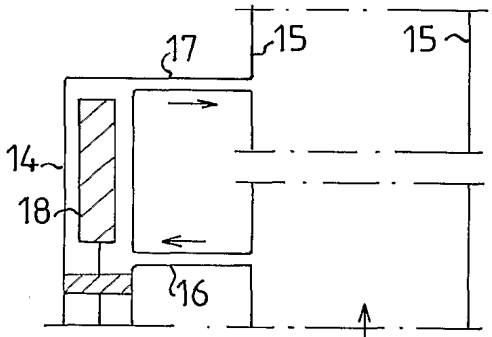


FIG. 2

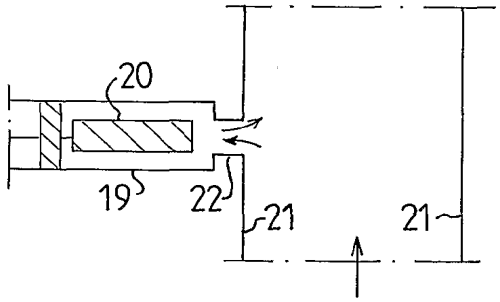
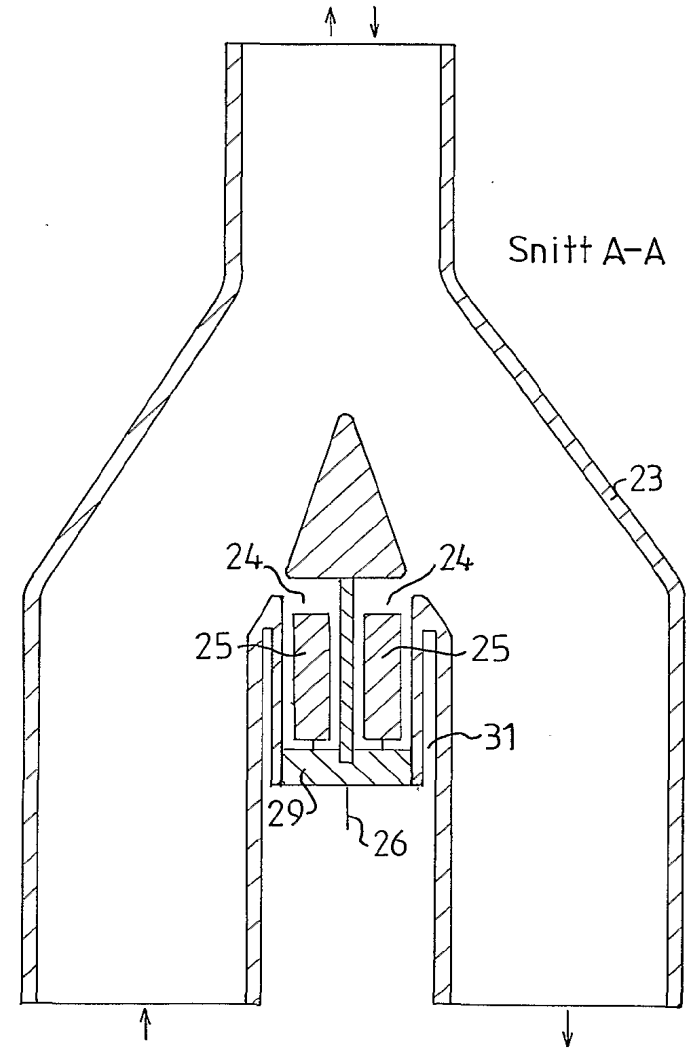


FIG.3



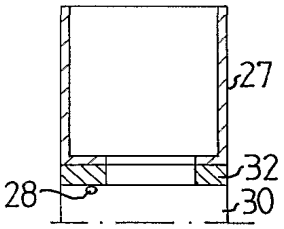


FIG. 5

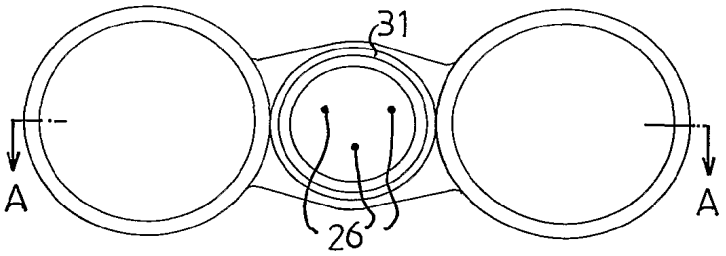


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 02/00802

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 16/16
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1005878 A2 (SIEMENS-ELEMA AB), 7 June 2000 (07.06.00), column 2, line 50 - line 58; column 3, line 29 - line 32, abstract	1,4,8,10
Y		2,9
	--	
Y	WO 9104067 A1 (THE UNIVERSITY COURT OF THE UNIVERSITY OF DUNDEE), 4 April 1991 (04.04.91), figure 1a	2,9
	--	
A	EP 0815891 A2 (INSTRUMENTARIUM OY), 7 January 1998 (07.01.98)	1-15
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☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
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Date of the actual completion of the international search	Date of mailing of the international search report
5 August 2002	08 -08- 2002
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Åsa Malm/MN Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

Information on patent family members

06/07/02

International application No.
PCT/SE 02/00802

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 1005878 A2	07/06/00	JP 2000167055 A	20/06/00
		SE 9804148 D	00/00/00
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		GB 8921800 D	00/00/00
EP 0815891 A2	07/01/98	FI 104312 B	00/00/00
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